

FDA Approves Desvenlafaxine, Once-Daily Serotonin-Norepinephrine Reuptake Inhibitor To Treat Major Depressive Disorder

MADISON, N.J., Feb. 29 /PRNewswire-FirstCall/ -- Wyeth Pharmaceuticals, a division of Wyeth, announced today that the U.S. Food and Drug Administration (FDA) has approved PRISTIQ(TM) (desvenlafaxine), a structurally novel, once-daily serotonin-norepinephrine reuptake inhibitor (SNRI), to treat adult patients with major depressive disorder (MDD). Wyeth expects to begin shipping PRISTIQ to wholesalers beginning in the second quarter of 2008.

"We are pleased to be able to bring PRISTIQ to patients," says Bernard Poussot, President and Chief Executive Officer of Wyeth. "PRISTIQ is Wyeth's fourth new drug to receive approval in the last twelve months, demonstrating our ability to achieve success through the rigorous scientific process of discovery and development. We look forward to working with FDA and other regulatory authorities around the world to continue to bring important new medicines to patients who need them."

"PRISTIQ is an important new therapeutic option for patients and clinicians because no single therapy works for all people with major depression," says Philip Ninan, M.D., Vice President of Wyeth Medical Affairs, Neuroscience. "PRISTIQ is approved at a once-daily 50-mg dose that does not require titration, allowing physicians to start their patients at the recommended therapeutic dose. We are encouraged by the tolerability profile seen in clinical studies."

FDA approval was subject to several post-marketing commitments, including conducting and submitting data from a new long-term maintenance (relapse prevention) study, a sexual dysfunction study, pediatric studies and a study exploring lower doses. The agency also requested an additional non-clinical toxicity study.

The efficacy of PRISTIQ as a treatment for depression was established in four 8-week, randomized, double-blind, placebo-controlled, fixed-dose studies in adult outpatients who met the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) criteria for MDD. At the recommended dose of 50 mg, the discontinuation rate due to an adverse experience for PRISTIQ (4.1 percent) was similar to the rate for placebo (3.8 percent).

Side effects of many antidepressant therapies can cause some patients to stop taking their medication. The most commonly observed adverse reactions in patients taking

PRISTIQ for MDD in short-term, fixed-dose studies (incidence greater than or equal to 5 percent and at least twice the rate of placebo in the 50 or 100 mg dose groups) were nausea, dizziness, insomnia, hyperhidrosis, constipation, somnolence (sleepiness), decreased appetite, anxiety, and specific male sexual function disorders.

About PRISTIQ

PRISTIQ delivers the major active metabolite of EFFEXOR XR(R) (venlafaxine HCl) in its active state without going through the CYP2D6 metabolic pathway. This could be beneficial when PRISTIQ is coadministered with other commonly prescribed medications metabolized through that pathway. EFFEXOR XR, discovered and developed by Wyeth, was the first SNRI approved by the FDA for MDD and is currently the most widely prescribed antidepressant in the world.

PRISTIQ, also discovered and developed by Wyeth, demonstrates the Company's significant and continued commitment to developing new therapies in the field of neuroscience.

About Major Depressive Disorder

Major depressive disorder (MDD) is a common mental disorder, affecting about 121 million people worldwide. In the United States, MDD affects approximately 15 million adults, or 6.7 percent of the U.S. population age 18 and older in a given year. In fact, depression is among the leading causes of disability and the fourth leading contributor to the global burden of disease. Further, a research study estimated that the total economic burden of depression was \$83.1 billion in 2000, including direct treatment costs and suicide- and work-related costs.

MDD is a serious medical condition that is different from "feeling blue" and is not something that people just "get over." Criteria for MDD include five or more of the following symptoms that have been present for at least two weeks, and at least one of the symptoms must be either depressed mood or loss of interest or pleasure: depressed mood; loss of interest or pleasure; changes in appetite or weight; changes in sleeping patterns; psychomotor agitation or retardation; fatigue or low energy; feeling worthless or guilty for no reason; difficulty thinking or concentrating; or thoughts of death or suicide. Further, people with MDD must experience clinically significant distress or impairment in social, occupational or other important areas of functioning.

Source: Wyeth Pharmaceuticals